REMARKS

Claims 2-6, 11, 13-20, 25 and 28-86 are pending in the Application. Claims 2-6, 11, 13, 14, 17 and 28-86 are rejected under the judicially created doctrine of obviousness-type double patenting. Applicants traverse the rejection for the reasons of record in Applicants' response to the non-final Office Action, and for the reasons set forth herein below, namely that no *prima facie* case of obviousness has been established with respect to the pending claims compared to the invention defined in the cited patent.

In view of the arguments below, Applicants request reconsideration on the merits, withdrawal of the finality of the Office Action, withdrawal of the rejections, and allowance of the claims.

Obviousness-Type Double Patenting Rejection

Claims 2-6, 11, 13, 14, 17 and 28-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent 6,130,346. As Applicants pointed out in their previous response, Applicants believe that the reference to U.S. Patent No. 6,130,346 is a typographical error, and that the Examiner intended to cite U.S. Patent No. 6,150,346 (the " '346 Patent"). **Applicants ask that the Examiner make the appropriate correction of the patent number on the record.**

Applicants respectfully submit that the final rejection is premature and request that the Examiner remove the finality of the rejection. Applicants respectfully submit that the Office Action does not meet the requirements set forth in MPEP 707.07(d), in so much as the Office Action fails to fully and clearly state the basis for rejecting the claims.

The Manual of Patent Examining Procedure (MPEP) provides, in relevant part, that "in determining whether a proper basis exists to enter a double patenting rejection, the examiner must determine .... (C) whether a nonstatutory basis exists. (MPEP 804, II). In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is—does any claim in the application define an invention that is merely an obvious variation of an invention *claimed* in the patent. A double patenting rejection of the obviousness type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103, except that the patent principally underlying the double patenting rejection is not considered prior art... Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness

determination, using the factual inquiries set forth in Graham v. John Deere." [MPEP 804, II.B.1] (emphasis added)

The MPEP further instructs:

"Any obviousness-type double patenting rejection should make clear:

(A) The differences between the inventions defined by the conflicting claims- a *claim* in the patent compared to a claim in the application; and

(B) The *reasons* why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent.

As such, assertions of such obviousness must be supported by valid prior art evidence.

To establish obviousness-type double patenting, the inventions defined in the claims of the '346 Patent and in the pending claims must first be identified. The inventions defined in the claims of the '346 Patent are:

"[a]n improved and stabilized previtamin D oral formulation, said formulation comprising a therapeutically effective amount of substantially pure, solvent-free crystalline 1α-hydroxyprevitamin D ...." (claim 1)

and

"[a] method for treating or preventing osteoporosis in a human being, comprising administering orally to said human being in need thereof an effective amount of the previtamin D oral formulation of claim 1." (claim 6).

The inventions defined in the claims at issue are:

"[a] method of achieving an effect in a in a patient comprising administering an effective amount of a vitamin D compound which is a 24-hydroxyvitamin D compound wherein the effect is treating or preventing bone loss or bone mineral content, ..." (claim 2)

and

"[a] method of achieving an effect in a patient comprising administering an effective amount of a vitamin D compound which is a 24-hydroxy*pre*vitamin D, wherein the effect is treating or preventing bone loss or bone mineral content, ..." (claim 3).

The claims of the '346 Patent define only "previtamin D formulation[s] comprising 1α-hydroxyprevitamin D" and a "method of treating or preventing osteoporosis" by "administering ...the previtamin D oral formulation." All previtamin D compounds defined in the claims are hydroxylated in the 1α-position. Claim 2 of the '346 Patent defines that the

previtamin D compounds may also be dihydroxylated, e.g., in the 1α-position and in the 24-position, such as "1α,24-dihydroxyprevitamin D_2" (see, claim 2 of the '346 Patent).

In contrast, the invention defined by the instant claims is a method of use of 24-hydroxylated vitamin D and 24-hydroxylated previtamin D, i.e., neither the previtamin nor the vitamin form are hydroxylated in the 1α-position. The Examiner nonetheless asserts that the invention claimed in the present application is merely a variation of the invention claimed in the '346 Patent such that the invention defined in the pending claims would have been obvious to one having ordinary skill in the pertinent vitamin D art. To establish that the invention claimed in the present application is an obvious variation of the invention defined in the claims of the '346 Patent, the Examiner must establish a prima facie case of obviousness. As such, any assertion of obviousness must be supported by valid prior art evidence.

At the outset, Applicants note that there is no prior art evidence of record. Specifically, nothing in the present record suggests modifying the invention defined in the claims of the '346 Patent to select the compounds of Applicants' pending claims nor that such selected compounds would yield results of the patented method. Even considering the 1α,24-dihydroxylated previtamin D compounds defined, e.g., in claim 2 of the '346 Patent, there is nothing of record that would have suggested to or motivated the skilled artisan to remove the 1α-hydroxyl group to yield a 24-hydroxy previtamin D, or further to convert the previtamin D form to the vitamin D form, i.e., to yield 24-hydroxy vitamin D, and have a reasonable expectation of achieving the same results of the method defined in the claims of the '346 Patent. Clearly, one having ordinary skill in the vitamin D art would not have concluded that use of the 24-hydroxyprevitamin D and use of the 24-hydroxyvitamin D are obvious variations of the invention defined in the claims of the '346 Patent.

Further, in the non-final Office Action and the final Office Action, the Examiner nonetheless asserts that "the patent claims 24-hydroxy Vitamin and 24 hydroxy preVitamin D compounds administered to treat diseases claimed in Applicants' claims 2-6, 11, 13, 17 and 28-35". With due respect, the instant compounds used in Applicants' claimed methods are nowhere recited or defined in the claims of the '346 Patent. The Examiner also asserts that "the teachings within the entire patent could have been calimed [claimed] by Applicants in the patent. For these reasons it would have made the claims obvious under 35 U.S.C 103" (emphasis added). The Examiner is understood to assert that, somehow, the cited patent teaches the invention of the instant claims and that that invention could have been claimed by Applicants in the cited patent. Again, Applicants respectfully submit that the instant

invention recited in Applicants' pending claims is nowhere in the teachings of the cited patent, and further, the disclosure of the '346 Patent may not be used as prior art in determining obviousness-type double patenting. Even if one would turn (impermissibly) to the disclosure of the '346 Patent, there is nothing in the teachings of the '346 Patent that suggests that formula (I) of that patent may be modified to remove the 1α-hydroxyl group and such compounds would reasonably achieve the same results as the patented methods.

The Final Office Action also directs Applicants' attention to the fact that the rejection is an obviousness type double patenting rejection and advises Applicants that this type of rejection is grounded in public policy to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent and to prevent possible harassment by multiple assignees.

Applicants do not dispute the public policy considerations underlying the establishment of the judicially created doctrine of obviousness-type double patenting. Nevertheless, the existence of this doctrine, however meritorious the underlying public policy concerns, does not absolve the United States Patent and Trademark Office of its burden of establishing a *prima facie* case of obviousness.

The Final Office Action further states:

"The compounds and method of use is obviated in the '346 patent which claims the previtamin D compounds as claimed Applicants claims. Applicants are directed to the formulae at columns 1 and 2 lines 36-54. These formulae appear to define the obviousness of Applicants' claims.

"Therefore, the rejection of December 16, 2002 is deemed proper and restated herein."

As Applicants pointed out in the previous response and reiterated herein above, it is the claims of the '346 Patent that define the invention against which the invention defined in the pending claims is compared. The formulae to which the Examiner refers are not defined in the claims of the '346 Patent, and are not properly cited as prior art evidence of obviousness.

In evaluating claims in a later filed application for obviousness-type double patenting over an issued patent, "a one-way obviousness determination is needed in resolving the issue of double patenting, i.e., whether the invention defined in a claim in the application is an obvious variation of the invention defined in a claim of the patent.... Unless a claimed invention in the application is obvious over a claimed invention in the patent, no double patenting rejection of the obvious-type should be made." (MBEP 804, II.B.1.a).

The MPEP further provides:

"When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the disclosure.

"The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." (MBEP 804, II.B.1)

As such, Applicants respectfully submit that it would be appropriate to refer to the specification for disclosure relevant to the construction of the term "1α-hydroxyprevitamin D", and Applicants direct the Examiner's attention to the formulae I and II, shown at columns 4 and 5. Applicants, however, are unclear as to why the Examiner asserted that the formulae shown in columns 1 and 2 of the '346 patent render the instant claimed methods obvious in the context of an obviousness-type double patenting rejection. Applicants direct the Examiner's attention to the fact that the structures shown in '346 patent at columns 1 and 2 are previtamin D_3 and vitamin D_3, respectively. Applicants wish to point out to the Examiner that, even if reference to the teachings of the specification were appropriate in an obviousness-type double patenting rejection, neither structure is hydroxylated at the C24 position. Although the MPEP instructs that the specification can be used to discern the meaning of a term in a claim, the meaning of the terms of the claims of the '346 patent is not informed by reference to the structures at columns 1 and 2. Applicants respectfully submit that, whereas the compounds of the claimed method of the instant application are not hydroxylated at carbon-1, those of the formulations and methods defined in claims of the '346 Patent are hydroxylated at carbon-1.

Because the cited art fails to teach or suggest use of the compounds according to the claimed methods, the rejection under the doctrine of obviousness-type double patenting is improper. Applicants respectfully request withdrawal of the rejection and allowance of the presently pending claims.

In view of the foregoing, reconsideration and allowance of claims 2-6, 11, 13, 14, 17 and 28-86 is respectfully requested. The Examiner is strongly encouraged to contact the undersigned by telephone should any issues remain with respect to the Application.

No fee is believed due in connection with this submission. However, if a fee is owed, please charge such fee to Deposit Account No. 50-0842.

Respectfully submitted,

Jill A. Fahrlander
Reg. No. 42,518

File No. 17620/9316

Michael Best & Friedrich LLP
One South Pinckney Street
P. O. Box 1806
Madison, WI 53701-1806
(608) 257-3501